

Appl. No. : 09/651,181
Filed : August 30, 2000

REMARKS

Applicants wish to thank the Examiner for the indicated withdrawal of the previous §102 and §103 rejections. Claims 1-10, 17-23, 29-31, and 48 are presented for examination. Reconsideration of the present case is respectfully requested.

Summary of Interview

Applicants wish to thank the Examiner for the courteous telephonic interview on March 1, 2004. During the interview, Applicants and the Examiner discussed the scope of the pending claims and the limitations of the art cited in the November 5, 2003 Office Action. While no agreement was made at the end of the interview, relevant issues regarding the patentability of the claimed invention were clarified. Applicants will now address these issues in more detail below.

Discussion of Rejection Under 35 U.S.C. § 103

The Examiner rejected Claims 1-8, 10, 17-23, 29-31, and 48 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,023,540 (Walt) in view of U.S. Patent No. 5,649,924 (Everett). Applicants respectfully disagree.

Non-Analogous Art

The Examiner asserted that Walt, et al. teach array compositions and that it would have been obvious to “combine and substitute a reflective layer coating the bottom of the well of Everett et al. into the method of Walt, et al.” However, in order to rely on a reference as a basis for rejecting Applicants’ invention, “the reference must either be in the field of applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the invention was concerned.” *In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992). As discussed below, Everett is not in the Applicants’ field of endeavor, nor is it pertinent to the problem addressed by the present application.

The field of Applicants’ endeavor is array compositions that are useful for detecting target analytes in a particular sample. Examples of array compositions include fiber optic and planar arrays of microspheres. In contrast, the field of endeavor for Everett et al. is medical devices and procedures that utilize a laser to locally heat tissue in a patient (*See* Everett, Field of the Invention). In Everett, the reflective layer is used to aim the laser within the medical device,

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whereas the recited array compositions use a reflective layer to increase the sensitivity of a detection assay. For these reasons, Everett is not within Applicants field of endeavor.

Furthermore, the teachings of Everett are not pertinent to the specific problem that Applicants' invention addresses. Applicants' claims relate to reflectively coating wells in order to enhance detection of fluorescent signals (*See* page 11, lines 18-21). In contrast, the laser energy source taught by Everett is designed to stop bleeding, destroy tissue, and make incisions in a patient. There is no signal detection step in Everett's disclosed methods (*See* Everett, column 5, lines 57-62). As the teachings of Everett are not concerned with signal detection, this reference does not address the problem of enhancing signal detection, as described in Applicants specification. For these reasons, Everett is not reasonably pertinent to the particular problem with which Applicants invention is concerned.

Moreover, the similarities and differences in structure and function of the inventions carry great weight in determining whether a reference is analogous prior art. *See* MPEP §2141.01(a) citing *In re Ellis*, 476 F.2d 1370, 1372 (C.C.P.A. 1973). In the present case, there are many differences between the function and structure of Applicants' claimed invention and the teachings of Everett. With respect to function, Applicants' claims relate to compositions having wells that utilizing a reflective coating in order to enhance the collection and detection of a light signal (*See* page 11, lines 18-21). In contrast, Everett teaches a reflective layer that converts a laser energy source into heat and re-directs the laser light to a desired location in the patient (*See* Everett column 6, lines 45-55, and Figures 9-12). As mentioned above, this energy is then used to stop bleeding, destroy tissue, or make incisions in a patient (*See* Everett, column 5, lines 57-62).

With respect to structure, Applicants' claims relate to array compositions having discrete wells wherein a reflective layer coating is placed within the wells to enhance signal detection. The teachings of Everett lack any type of wells, much less wells configured to hold a microsphere. Furthermore, Everett fails to disclose any type of microsphere or any apparatus related to analytical compositions. Thus, the structure of the device disclosed in Everett is very different from Applicants claimed array compositions.

For all of the reasons discussed above, it is clear that the teachings of Everett are in a different field of art, and address a different problem, than Applicants' claimed invention. Accordingly, it is improper to rely on Everett as a basis for a §103 rejection. Thus, Applicants

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respectfully request removal of Everett as a prior art source, and withdrawal of this rejection under 35 U.S.C. § 103(a).

The Examiner Has Not Made a Prima Facie Case

Even if Everett is relied upon by the Examiner, a proper *prima facie* case of obviousness has not been made. To establish a *prima facie* case of obviousness a three-prong test must be met. First, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success found in the prior art. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Applicants respectfully submit that there is no motivation or suggestion to modify the cited art to achieve the claimed invention. Everett would not have motivated a skilled artisan to modify the device of Walt to achieve wells having reflective coatings because such a combination would not have worked for its intended purpose. The Federal Circuit has held that if a proposed modification would render the invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification (*In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984)). In the present case, adding a reflective coating to the fiber optic arrays taught by Walt would have rendered them unsatisfactory for their intended purpose.

Walt discloses a fiber optic array, wherein the beads are located at the distal end of the fiber optic. The optical signal is transmitted to, and collected at, the proximal end of the fiber optic (See Walt column 3, line 61 to column 4, line 3). Thus, in order for the array of Walt to be operable, the light signal from a fluorescent microsphere is transmitted along each fiber optic line to a detector at the proximal end. For this reason, placing a reflective coating on the distal end of the fiber optic would significantly impede, if not completely block, any signal collection at the proximal end. Because Walt is primarily directed to detection assays, any hindrance of the signal collection process would effectively render these assays unsatisfactory for their intended purpose.

This contrasts with Applicants disclosure of planar and fiber optic arrays where the detector is placed opposite the distal end of the fiber optic, and thus does not require the fluorescent signal to traverse the fiber optic line. (See page 4, lines 28-32). When using Applicants claimed array compositions, one does not detect the fluorescent signal through the

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optical fiber. Applicants' fiber optic bundles or planar substrates provide the microsphere wells, and according to the teachings of the specification, the fluorescent signal is not read through the fiber optic lines (*See* page 47, lines 31-34). As Walt is directed to proximal end fiber optic imaging, and does not suggest any motivation or benefit for utilizing distal end imaging, applying a reflective coating to the Walt arrays would effectively render them unsatisfactory for their intended purpose. For these reasons, the Examiner has not made a proper *prima facie* case of obviousness.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *See* MPEP §2143.01. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

With these rules in mind, the Examiner has not properly identified any teaching or suggestion within Walt, Everett or the generally available knowledge that would motivate a skilled artisan to reflectively coat the wells of Walt. It is first noted that Walt and Everett are distinct technologies designed to perform completely different tasks. Walt relates to fiber optic arrays having encoded microspheres that transmit signals from a distal end of a fiber optic to a proximal end, where they are detected (*See* Walt, Abstract, and column 3, line 62 to column 4, line 3). In contrast, Everett is directed to medical devices and procedures that utilize heat and lasers to stop bleeding, destroy tissue, or make incisions in a patient (*See* Everett, Field of the Invention, column 5, lines 57-62). Thus, the teachings of Everett disclose a reflective layer used for a completely different purpose than Walt.

In light of the Examiner's assertion that Everett provides the motivation to modify the wells disclosed in Walt, it is important to note that Everett fails to disclose any type of signal detection step in their disclosed methods. Given the lack of disclosure on signal collection, Applicants argue that a skilled artisan would not have been motivated to enhance signal detection upon reviewing the Everett reference. Thus, a skilled artisan, having reviewed Everett, would not have been motivated to add a reflective layer to enhance signal collection of the array compositions of Walt.

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Nor is the motivation to add reflective coatings found within the teachings of Walt. As discussed earlier, Walt is directed to proximal end imaging. Accordingly, placing a reflective coating on the disclosed fiber optic arrays would render Walt unsuitable for its intended purpose of signal detection. Thus, a skilled artisan, having reviewed Walt, would not have been motivated to add a reflective layer to enhance signal collection.

As neither Walt nor Everett provide any motivation or suggestion to make the needed modifications, and the Examiner has failed to cite any motivation within the generally available knowledge, a proper *prima facie* showing of obviousness has not been made. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claim 9

The Examiner rejected Claim 9 under 35 U.S.C. § 103(a) as being unpatentable over Walt, in view of Everett, and further in view of U.S. Patent No. 5,896,227 (Toriumi). Applicants respectfully disagree.

As described in detail above, the combination of Everett and Walt would not have made the claimed invention *prima facie* obvious to one of ordinary skill in the art. With respect to Toriumi, the Examiner asserted that the dielectric coated wells recited in Claim 9 would have been obvious in light of Toriumi. However, this reference teaches microspheres having a dielectric coating, and not wells having a dielectric coating. Toriumi's disclosure of dielectrically coated microspheres would not motivate a skilled artisan to coat the *wells* of Walt with a dielectric material, as it would render the teachings of Walt unsuitable for their intended purpose, as described in detail above. Accordingly, for all of the reasons discussed above, Applicants respectfully request the withdrawal of the §103 rejection of Claim 9, and allowance of all of the pending claims.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, arguments in support of the patentability of the pending claim set are presented above. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

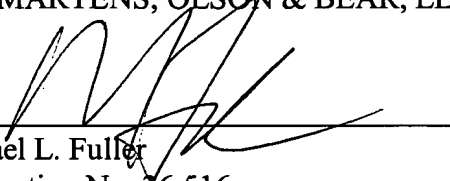
Respectfully submitted,

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Dated: _____

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